REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

By way of this amendment, claims 1-36 are pending. Claims 1, 16, and 33 has been amended to remove the term "preventing." Claim 33 has been amended to become an independent claim as requested by the Examiner. Claims 25, 27, 29, and 30 have been amended to correct a typographical error. New claims 35 and 36 have been added to further describe the pharmaceutical composition of claim 33. Support for new claims 35 and 36 can be found, for instance, at pages 15 and 16 of the present application. Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

Election/Restriction Requirements

The Examiner has requested that the claims be amended to the elected/rejoined group, including the elected compound.

In response, the applicant will make such an amendment upon an indication of allowable subject matter.

Rejection of claims 33 and 34 under 35 U.S.C. §102(b) -- Powers et al.

At page 2 of the Office Action, the Examiner rejects claims 33 and 34 under 35 U.S.C. §102(b) as being anticipated by Powers et al. (U.S. Patent No. 5,543,396). The Examiner asserts that Powers et al. teaches a pharmaceutical composition in any form comprising the elected compound, and the Examiner makes reference to the "tissue remodeling" at col. 1, lines 41-43 of Powers et al. and appears to equate this "tissue remodeling" to include tissue adhesion formation.

The rejection in its entirety is respectfully traversed.

Claim 33 of the present application recites a pharmaceutical composition for the prevention of adhesion formation, which comprises at least one protease inhibitor and a pharmaceutically acceptable diluent or excipient. Claim 34 further comprises a delivery vehicle, which maintains an effective local concentration of the protease inhibitor at the site on a tissue surface for a period of time sufficient to reduce adhesion formation.

Unlike the present invention of claims 33 and 34, Powers et al., while relating to a pharmaceutical composition and mentioning the inhibitor of a chymase, does not teach or suggest the pharmaceutical activities of reducing adhesion formation with the use of this composition. With respect to claim 33, Powers et al. does not show a composition for prevention of adhesion formation. Contrary to the Examiner's assertions at the top of page 3 of the Office Action, tissue adhesion formation is quite different from tissue remodeling. The applicant traverses the Examiner's position on this matter. Powers et al. does not teach or suggest that tissue remodeling encompasses tissue adhesion formation, and one skilled in the art would readily recognize the difference between tissue remodeling and tissue adhesion formation. Tissue remodeling generally involves the remodeling or rebuilding of damaged tissue, which, many times, is carried out through changing the formation of the tissue itself. For example, in bone tissue remodeling, remodeling can be done with the use of calcium metabolism and can be regulated through the balance of biosynthesis and degradation of ECM by osteoblasts and osteoclasts, respectively.

As indicated in the present application, adhesion formation many times occurs through surgical procedures, wherein the adhesion can result from a wound healing response. As described at the bottom of page 1 and top of page 2 of the present application, adhesion formation and adhesion-free re-epithelialization are alternative pathways, both of which begin with coagulation

and which can result in the build-up of fibrin gel matrix, and if this fibrin deposition is in excess or not removed, the gel matrix serves as a progenitor to adhesions by forming a band or bridge when two tissue surfaces coated with fibrin matrix are apposed. This is quite different from tissue remodeling.

Furthermore, with respect to claim 34, there is no teaching or even a suggestion in Powers et al. regarding the presence of a delivery vehicle which can maintain an effective local concentration at the site on a tissue surface. Powers et al. merely describes a tablet or aqueous or oily suspension which would not be a teaching or a suggestion of a delivery vehicle which can maintain an effective local concentration of the protease inhibitor at the site on a tissue surface for a period of time sufficient to reduce adhesion formation.

New claims 35 and 36 further distinguish aspects of the claimed invention from Powers et al. in that claims 35 and 36 recite the presence of a microcapsule or microsphere with a biodegradable polymer which clearly is not taught or suggested in Powers et al., nor does Powers et al. teach or suggest that the pharmaceutical composition is in the form of a film which contains a biodegradable polymer or liposome. Again, Powers et al. is not concerned with applying a substance to the site of a tissue surface.

Accordingly, this rejection should be withdrawn.

Rejection of claims 1-34 under 35 U.S.C. §103(a) over Powers et al. in view of Scharpe et al.

At page 3 of the Office Action, the Examiner rejects claims 1-34 under 35 U.S.C. §103(a) as being unpatentable over Powers et al. in view of Scharpe et al. (U.S. Patent Application Publication No. 2002/0061839 A1). The Examiner relies on Powers et al. as described above in the §102 rejection. The Examiner does acknowledge in this rejection that Powers et al. does not expressly

teach the use of the elected peptide to reduce adhesion formation or the various forms of administration set forth in claims 25-30. The Examiner relies on Scharpe et al. to assert that Scharpe et al. uses serine protease inhibitors in virtually any pharmaceutical mixture/formulation. This rejection in its entirety is respectfully traversed.

With respect to this §103 rejection, the points regarding Powers et al. above apply equally here. Powers et al. does not teach or suggest a method of using a protease inhibitor to reduce adhesion formation. As indicated above, Powers et al. makes reference to tissue remodeling, but tissue remodeling is not equivalent or a genus of treating adhesion formation as indicated above. The primary purpose of Powers et al. is to use certain derivatives as anti-coagulants, anti-inflammatory agents, and anti-tumor agents. As indicated, while there is a mention of tissue remodeling and topical applications, tissue remodeling is quite different from the reduction of adhesion formation of tissue as indicated above.

Furthermore, Scharpe et al. does not overcome the deficiencies of Powers et al. As indicated above, Scharpe et al. does not teach or suggest treating adhesion formation.

It is important to note that in reducing or treating adhesion formation, the protease inhibitor is typically placed at the site where surgery occurs, for instance, as recited in claim 16 (and even claim 1) of the present application. Neither Powers et al. nor Scharpe et al. have any teaching or even a suggestion of applying a protease inhibitor to a site on a tissue surface to reduce adhesion formation.

Further, it is unclear whether one skilled in the art would look to Scharpe et al. to modify the compound of Powers et al. when Powers et al. makes no teaching or suggestion to make such a modification and, further, the particular administration routes set forth in Powers et al. are very clear with respect to use of the derivatives of Powers et al. as anti-coagulants, anti-inflammatory agents,

and anti-tumor agents.

The applicant would appreciate discussing this matter with the Examiner by telephone should the Examiner have any questions regarding the differences between the uses set forth in Powers et al. and the particular methods claimed in the present application.

Accordingly, this rejection should be withdrawn.

Provisional Rejection -- Obviousness-Type Double Patenting

At page 5 of the Office Action, the Examiner provisionally rejects claims 1-34 on the ground of obviousness-type double patenting as being unpatentable over claims 1-20 of co-pending U.S. Patent Application No. 10/544,254. This provisional rejection is respectfully traversed.

Since this is a provisional rejection, once the remaining rejections described above have been overcome, this provisional rejection should be withdrawn and, if necessary, applied in co-pending U.S. Patent Application No. 10/544,254.

The applicant does note that in U.S. Patent Application No. 10/544,254, the application relates to administering a protease inhibitor intravenously, orally, or percutaneously. These modes of administration are not recited in the claims of the present application.

Accordingly, this provisional rejection should be withdrawn once it is the only remaining rejection in the present application.

Rejection of claims 1-34 under 35 U.S.C. §112, first paragraph

At page 6 of the Office Action, the Examiner rejects claims 1-34 under 35 U.S.C. §112, first paragraph, for enablement reasons. The Examiner believes that reference to "preventing" adhesion formation is not enabled by the present application. This rejection is respectfully traversed.

Applicant believes that the application is enabling for the scope provided in the pending claims. To assist the Examiner, the claims have been amended to remove reference to "preventing" since a method for reducing adhesion formation will embrace the same scope. Further, the present application teaches that the present application relates to treating adhesion formation.

Accordingly, this rejection should be withdrawn.

Rejection of claim 33 under 35 U.S.C. §112, second paragraph

At page 7 of the Office Action, the Examiner rejects claim 33 for indefinite reasons. The Examiner asserts that this claim, which is a product claim, depends upon a method claim. This rejection is respectfully traversed.

Claim 33 has been amended to become an independent claim to address the Examiner's concerns. The scope of the claim remains the same. Accordingly, this rejection should be withdrawn.

Objection to claim 34

At the bottom of page 7 of the Office Action, the Examiner objects to claim 34 as being in improper form because it depends upon a multiple dependent claim.

In response, by way of amendment of claim 33, which is now an independent claim, claim 34 is in proper format. Accordingly, this objection should be withdrawn.

With respect to the Examiner's observations concerning the mis-spelling in claims 25, 27, 29, and 30, these corrections have been made. The applicant appreciates the Examiner's observations.

With respect to claims 25-30, the applicant will be willing to re-arrange the numbering of

the claims upon the allowability of the subject matter of the present application.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

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